GHS Public Meeting Summary
(October 18-19, 2006)

On October 18-19, 2006, EPA's Office of Pesticide Programs convened a public stakeholder meeting to discuss the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as it relates to pesticide products that are registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The goals of the workshop were to discuss and clarify the scope and potential application of GHS to pesticide products; to examine key issues raised in public comments on OPP's GHS White Paper; to gain a better understanding of stakeholder concerns and explore ways to address them; and to assess potential paths forward to maximize benefits and minimize costs.

Over one hundred participants attended the meeting, representing industry, trade associations, environmental groups, and state, federal, and international regulatory agencies. Attendees participated actively in discussions, which enabled the goals of the workshop to be met, as summarized below. On many issues, stakeholders expressed divergent views and engaged in dialogue aimed at resolving differences.

Goal 1: Discuss and clarify scope and potential application of GHS to pesticide products

EPA presentations clarified the scope and potential application of GHS to pesticide labels, and discussed the value of the new system in terms of improving public health and environmental protection and eliminating potential confusion resulting from differences in existing classification and labeling systems, both domestically and at the international level. Environmental advocates and industry representatives detailed their views and concerns about GHS. Other presentations focused on potential impacts on State regulatory systems, training and outreach needs, and plans for implementation of the GHS in Canada. (Please see Agenda for full list of presenters and for their presentations). A question and answer and open discussion session followed each panel presentation.

Goal 2: Examine key issues raised in response to GHS White Paper
Goal 3: Gain a better understanding of stakeholder concerns and explore ways to address them

Goals 2 and 3 were met primarily through open discussion with the stakeholders in attendance. The following chart captures a variety of stakeholder views, reflecting both expected benefits and concerns of the adoption of GHS. It also captures OPP's initial thoughts on many of the points that were raised.

Issue/Concern	Stakeholder Views	EPA Observations
Need to re-classify products using GHS criteria	• May be difficult to locate data for some products; may have to "pull data out of storage" for older chemicals. • Current pesticide categories have been in place for 30 years, so employees responsible for classification will require retraining.	• To a large extent, data required for GHS classification are needed to complete product reregistration. • EPA has done design work for a database of the relevant study data and associated GHS label elements. • Once populated, such a database could be used by registrants and OPP, making classification and labeling changes much easier.
Label appearance/ redesign to make GHS changes	• Labels are already cluttered. • Many labels are already very tight on space and may not have room for additional GHS information. • Many participants acknowledged the potential benefit of pictograms in increasing the effectiveness of labels. • Having a red border on pictograms will add cost. • Many labels are in color now, so cost shouldn't be a significant factor. • Red is important because it is obvious. • Should try to come up with a less crowded, simpler label.	• GHS information would generally replace, not add to, existing label information (signal word, hazard and precautionary statements, product and supplier identifiers) • EPA is seeking input on label placement and organization issues. GHS does not include specifics, beyond stating that GHS information should appear together. • The most visible change for U.S. pesticide labels would be the use of more pictograms. • EPA originally suggested uniform use of a red pictogram border to attract attention and simplify compliance. • GHS provides the option of using a black pictogram border if the product is not traded internationally. • EPA will continue to seek input and work with stakeholders to improve labels and find ways to minimize incremental costs of GHS. • No intention of requiring re-labeling; existing stocks provisions would be included in any implementation plan.

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Potential effects on testing	• Registrants may reformulate and retest to avoid more "severe classification", even if this is not required. • GHS cut-offs are not the same as studies previously conducted under OECD guidelines, and new guidelines for some studies will only provide range data instead of point estimates for use in applying GHS cut-offs. • Organisation for Economic Co-operation and Development (OECD) is updating test guidelines and is aware of the question of converting range data to point estimates.	• GHS discourages new animal testing and emphasizes use of existing data. • GHS is intended to be testing- and test-method neutral for health and environmental effects • EPA has no intention of changing data requirements as a consequence of GHS adoption. • Registrants may retest and/or reformulate to try to achieve lower classification category under any system. • Guidance on how existing test results would be interpreted may alleviate concerns (e.g., clarify that there is no need to test beyond existing limit doses to achieve "unclassified" status). • GHS includes a range/point estimate conversion table.
Scope of hazard classes/categories covered	• EPA should not expand labeling beyond those hazards now covered. • EPA should adopt GHS labeling for chronic hazards– research is showing association between pesticide exposure and chronic health effects. • We should closely watch other countries to see what they will do regarding chronic health hazards. • GHS has more categories within a given hazard class; this will require more training and education.	• For policy and practical reasons, the GHS work group recommended limiting changes under consideration to those required for GHS-consistency, and not to expand the scope of current hazard labeling. • There are no plans to incorporate additional GHS hazard classes (e.g., carcinogenicity) at this time. • As a practical matter, additional categories do not necessarily require different labeling (e.g., GHS acute toxicity Categories 1 and 2 have the same label elements).
Scope of pesticide products covered	• GHS makes more sense for some types of pesticides than others. • EPA's current system is better than GHS. Agricultural pesticides are adequately labeled now and should not be covered in their final product form; could consider GHS for manufacturing-use	• GHS was intended to cover all types of chemicals, consistent with the U.S. system of regulation (pharmaceuticals, cosmetics may not be covered in the consumer use setting, but would be covered in the workplace and in transport).

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	products and antimicrobials. • GHS would be an improvement and could enhance common understanding for all types of pesticides. Major chemical exposures occur in agriculture. • The definition of pesticide varies across countries, so implementation of GHS for pesticides may not mean harmonized coverage, e.g., the EU regulates crop protection chemicals and biocides under different authorities, some countries consider some of the products EPA regulates as pesticides as animal drugs.	• EPA could consider staged implementation approaches, although realization of the benefits of improved consistency could be compromised or delayed. • Product characteristics and/or anticipated conditions of use could justify continuing current exemptions (e.g., certain indoor residential use products that are unlikely to be released in significant amounts into the aquatic environment are not now labeled for aquatic toxicity). • Agriculture has been identified as a key sector in capacity-building activities. • There are differences/ "grey areas" in definitions. We will be monitoring and coordinating with trading partners. EU proposal for GHS includes crop protection products and biocides, but unsure about animal drugs.
Pictograms	• Wide agreement that pictograms can be effective in increasing pesticide label comprehension. • Some of the GHS pictograms are new, and not widely understood or intuitive. • Pictograms may not fit on small packages. • It may be beneficial to focus training on pictograms rather than signal words. • Pesticide users may assume the product has changed if it bears a new pictogram, or that it is more hazardous than a competing product that has not yet changed its label.	• Research indicates that simple is better, and symbols are simple. • Pictograms can be effective in conveying message, especially combined with words. • New symbols require training, but there are many examples of non-intuitive symbols that are now widely understood based on education and widespread use. • Labels have changed to incorporate new or revised precautionary information in the past. Timing of changes can help promote a "level playing field," especially when accompanied by education and outreach efforts.

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Signal Word Changes	• Trainers of agricultural workers have found it difficult to successfully communicate the distinction between "Caution" and "Warning" so the elimination of "Caution" makes hazards clearer. • Literature that advises users to look for the signal word "Caution" would need to be changed. • Users may perceive there is a greater hazard when a product's signal word changes from "caution" to "warning," even if there has been no change in the product, causing an unfair competitive situation. • Purchasing policies and other downstream effects may be driven by signal words. • Some states may have regulations tied to signal words (e.g., schools or public offices may only use cleaning products with signal word "Caution" or no signal word).	• Research has shown that consumers generally do not distinguish between "Caution" and "Warning." • "Caution" and "Warning" are currently used interchangeably on non-pesticide consumer chemical labels. • Trained pesticide applicators may understand the difference between "warning" and "caution" in EPA's current labeling scheme. • Timing of changes can help prevent inequities in labeling of similar products, and should be accompanied by training. • EPA has evaluated its internal policies and requirements to determine those that will require change, and some commenters have also provided information. • We need to learn more about other potential secondary or downstream effects in order to assess how this issue may be addressed.
Training, Education and Outreach	• Implementation will require sufficient time and resources for education and training. • Training budgets are strained and facing cutbacks. • Some states use EPA core manual for training, so additional cost for them should be minimal. • Dealers could be an important avenue for education of purchasers of pesticide products. • GHS will increase public health and environmental protection only if symbols are widely understood. • Many workers move to different countries – GHS offers way to avoid having to retrain workers on symbols that vary by country. • Focus on changes in signal words and new pictograms.	• EPA agrees that training and education will be essential to successful implementation. • Efforts will have to be aimed at professionals and consumers/the general public • .We have involved pesticide educators and state officials in planning efforts to date and will continue to work with them as consideration of GHS implementation proceeds, including questions of timing to permit training and outreach. • There may be synergies with educational efforts and training materials developed by other agencies, e.g., Occupational Safety and Health Administration (OSHA) and Canada's PMRA • EPA is committed to stakeholder outreach.

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Implementation options: "Routine Business" model (registrants would make GHS label changes when they are already changing labels for other reasons) v. a separate approval process	• Many registrants would be reluctant to be first to make GHS changes. • A deadline would be necessary, and this could over-whelm the system if many registrants wait until the end of the implementation period. • Could result in same type of products, with similar hazards but different labels. • This could lead purchasers to conclude one product is more hazardous than another, creating an unfair competitive situation. • Industry needs a "level playing field."	• EPA initially favored this approach as least resource-intensive for registrants and EPA reviewers. • A separate approval process, like that used for first aid and worker protection statements, would be more costly in terms of agency resources, and could require registrants to incur costs of changing labels before they ordinarily would. • EPA agrees on the need to avoid over-whelming the label review system. • Important to balance costs and equity concerns • To achieve equity goals, could mix "Business as Usual" and a deadline for all to make changes: labels could be approved using a routine business model, but GHS changes would not have to appear on labels until the deadline.
Hybrid implementation options based on grouping like products	• This approach would be the most fair in the market and was recommended by some industry commenters who were concerned about equity in GHS application. • How would it work for products with multiple uses/sites? • EPA has successfully used this approach in other review programs. • Should have public list of when the groupings of products will be due for GHS label so registrants know where they fit in to the schedule.	• EPA is open to suggestions on how to make such a hybrid proposal work without unfairly disadvantaging registrants or over-whelming EPA reviewers. • Product grouping would affect the registering divisions; would need to carefully consider how to avoid swamping one branch at a time. • Staggered review schedules could be coupled with a single effective date for like products. • Products could be grouped by their primary use if multiple uses/sites.

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Notification vs. EPA label amendment review and approval	• If only GHS changes were involved, notification could be the fastest and easiest way and would not burden reviewers. • If the registrant only made GHS changes, would EPA limit review to only GHS portion of the label? • Notification is good idea, but may be more difficult for aquatic toxicity.	• EPA is open to the possibility of simplified procedures if the Agency can be assured that they will result in appropriate transition to the GHS. • Notification is an attractive option, but there have been problems in the past even when registrants stated that they were only making the EPA-required changes. • When labels came in for worker protection, over 50% of product labels included other changes as well. • If EPA finds an incorrect or violative label, the Agency can not ignore it. • Electronic label submissions would make review much quicker and easier, but this system is not now in place.
Value of pilot project proposals	• It would be helpful to gain experience by piloting GHS. • Participation should be voluntary. • Antimicrobial sector in particular is interested in participating in a pilot label project. • Some stakeholders volunteered to take the lead, including building on their consumer communication strengths to develop educational materials. • Could registrants make changes voluntarily, even if EPA does not require GHS?	• EPA would like to explore pilot activities with interested stakeholders. • Need to take sometime to define projects • Could be very simple, or more elaborate depending on level of interest • Would be worthwhile to consider variety of products • Registrants can not make GHS label changes on their own; it is possible that a pilot could be structured to permit GHS labels in some instances.
Fees	• Registrants should not have to pay Pesticide Registration Improvement Act (PRIA) fees, since GHS changes would be EPA initiated changes. • Concerns that state fees might constitute the bulk of GHS implementation costs were expressed in a written comment. • EPA needs to work with States so that there will not	• PRIA fees would not apply to Agency-initiated GHS label changes. Voluntary reformulations or other changes that may require a new product registration may incur fees. • It would be helpful to assure States that there are no changes in the product, only GHS label changes.

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	be fees charged. • Some states require a market place label, along with an EPA approved label simultaneously. Electronic labeling could help with this. • In DE, and other states that have commented, EPA-initiated label changes go through as amended labels, and no fee is charged.	• Initial findings (seven states): fees would not be charged by states for GHS changes. • The Agency would plan to coordinate with state counterparts to minimize the burden on their regulatory systems and avoid additional fees.
Overall cost of GHS implementation	• GHS implementation would mean major costs for registrants to come into compliance with the new rules. • Education and training costs need to be factored into cost estimates. • EPA should perform a thorough cost-benefit analysis before proceeding to implement the GHS, and should proceed only if benefits outweigh costs.	• The cost of implementation would vary tremendously depending on how it is done and within what time frame. • Most companies revise the labels of their products from time to time; if GHS implementation were to coincide with already-scheduled revisions, costs would be lower. • EPA would like to have more information on customary business practices, for large and small businesses. • EPA would need to amend regulations to require GHS changes. This requires thorough cost and impact analyses as part of the rule-making process.
Coordination and Stakeholder Participation	• U.S. timing is important, as we should be taking a leadership role. Momentum is lost when countries start according to different timetables. • Consider using Pesticide Program Dialogue Committee (PPDC) workgroups to gain stakeholder participation. • Should coordinate with North American Free Trade Agreement (NAFTA) labeling workgroup to develop pilot label. • Canada may find it difficult to move ahead without the U.S.; they are strongly urging U.S. adoption of	• Ongoing interagency coordinating group includes all four core regulatory agencies (EPA, OSHA, Department of Transportation (DOT), Consumer Product Safety Commission (CPSC)). • OSHA has designated GHS as a priority rule-making. • DOT is on track to implement most GHS changes by 2008 goal that was set by international groups. • GHS is part of ongoing NAFTA discussions

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	GHS. • Coordination would need to take place between EPA and OSHA to train anti-microbial users. • It could create problems if labels do not match information on material safety data sheets required by OSHA. • CPSC coordination is important, since they regulate non-pesticide consumer chemicals, some of which are also marketed as pesticides.	and is on the agenda of NAFTA TWG and stakeholder meetings. • EPA is also discussing implementation questions with other countries in OECD PWG and the UN Sub-Committee of Experts on the GHS. • Agree that continuing coordination and enhancing stakeholder participation is essential.

Goal 4: Assess potential paths forward:

In wrapping up the two-day meeting, EPA recognized that keeping stakeholders informed and involved will be essential as consideration of GHS proceeds. EPA also identified initial steps it would take to follow up on the points raised by the wide range of stakeholders who participated, communicate the results of the meeting, and assess future directions. In conclusion, EPA agreed to the following:

- Making background materials and presentations from the meeting widely available;
- Capturing the meeting in a summary;
- Continuing to meet and coordinate with others, including OSHA and other key U.S. agencies, stakeholders, and international entities;
- Weighing options for paths forward:
  - Researching the extent to which regulations and programmatic infrastructure could be affected;
  - Gathering data to help inform decisions;
  - Reviewing the potential benefits of GHS and other priority activities that require OPP attention and resources;
  - Exploring proposals for pilot activities as suggested by participants;
- Keeping stakeholders advised of progress.